



Serial No. 10/790,562

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hateboer *et al.*

Serial No.: 10/790,562

Filed: March 1, 2004

For: RECOMBINANT PROTEIN
PRODUCTION IN A HUMAN CELL

Confirmation No.: 9903

Examiner: W. Schlapkhol, Ph.D.

Group Art Unit: 1636

Attorney Docket No.: 2578-4038.3US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number _____

Date of Deposit with USPS: _____

Person making Deposit _____

BUDAPEST TREATY DECLARATION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ronald Brus, hereby certify that I am the Chief Executive Officer of Crucell Holland BV ("Crucell") and declare that:

1. I am informed and believe that Crucell is the assignee of U.S. patent application 10/790,562 entitled RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL.

2. As evidenced by the attached Deposit Receipt, I am informed and believe that Crucell's predecessor in interest made a deposit of the PER.C6™ cell line, under ECACC deposit number 96022940 under the provisions of the Budapest Treaty with the Centre for Applied Microbiology and Research Authority (European Collection of Animal Cell Cultures), Porton Down, Salisbury, Wiltshire SP4, OJG, United Kingdom, an International Depository Authority, on February 29, 1996.

3. On behalf of Crucell, I state that all restrictions upon public access to the deposit (except those restrictions permitted by 37 C.F.R. § 1.808(b)) will be irrevocably removed upon the grant of a U.S. patent on this U.S. patent application, and the deposit will be replaced if viable samples cannot be dispensed by the depository.

4. I am informed and believe that the deposit was accepted by the International Depository Authority, effective at least as early as February 29, 1996.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the patent.

6. Attached is a copy of the deposit receipt for ECACC deposit number 96022940.

Date: May 16, 2006



Ronald Brus



Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture
(Deposit Ref. 96022940) has been accepted as a patent deposit,
in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on 29TH February 1996

P J Packer

.....
Dr P J Packer
Quality Manager, ECACC



European Collection of Cell Cultures, CAMR, Salisbury SP4 0JG UK

Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 Email: ecacc@camr.org.uk Web Site: ecacc.org.uk

APPENDIX 3

Page 14

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

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INTERNATIONAL FORM

CRUCELL HOLLAND B.V.
ARCHIMEDESWEGL 4
PO BOX 2048
2301 CA LEIDEN
THE NETHERLANDS

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: PER C6	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 96022940
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
<p>The microorganism identified under I above was accompanied by:</p> <p><input checked="" type="checkbox"/> A scientific description <input type="checkbox"/> A proposed taxonomic designation</p> <p>(Mark with a cross where applicable)</p>	
III. RECEIPT AND ACCEPTANCE	
<p>This International Depository Authority accepts the microorganism identified under I above, which was received by it on 29th February 1996 (date of the original deposit)¹</p>	
IV. RECEIPT OF REQUEST FOR CONVERSION	
<p>The microorganism identified under I above was received by this International Depository Authority on _____ (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on _____ (date of receipt of request for conversion)</p>	
IV. INTERNATIONAL DEPOSITORY AUTHORITY	
Name: Dr P J Packer	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized officials(s):
Address: ECACC CAML Porton Down Salisbury SP4 0JG	Date: 26/2/01 PS Blacked

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

APPENDIX 3

Page 24

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
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INTERNATIONAL FORM

TO

CRUCELL HOLLAND B.V.
ARCHIMEDESWEGL 4
PO BOX 2048
2301 CA LEIDEN
THE NETHERLANDS

VIABILITY STATEMENT
Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITORY AUTHORITY
identified on the following page

NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY OF STATEMENT
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: CRUCELL HOLLAND B.V.	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 96022940
Address: ARCHIMEDESWEGL 4 PO BOX 2048 2301 CA LEIDEN THE NETHERLANDS	Date of the deposit or of the transfer: 29 th February 1996
III. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> viable <input type="checkbox"/> no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

Appendix 3

Page 25

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED

V. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Address:	Dr P J Packer ECACC CAMR Porton Down Salisbury Wiltshire SP4 0JG	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s): Date: 26/2/01 PShule
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4 Fill in if the information has been requested and if the results of the test were negative.